REMARKS

Claims 54-63 are currently pending in this application. Independent claims 54 and 61 are amended by this Response. Claims 1-53 have been previously cancelled.

NOVELTY

Applicant thanks the Office for its withdrawal of the rejection of the claims under 35 U.S.C. § 102(e) as anticipated by Gresser *et al.*

In the Office Action, dated January 15, 2004, paper no. 12 (hereinafter "OA"), claims 54-63 stood rejected under 35 U.S.C. § 102(e) as anticipated by Pickett *et al.* Claim 54 claims a drug delivery system comprising, among other things, a flexible pad containing a plurality of release pads with each release pad containing an electroactive polymer and medication. Contact points are operatively connected to the release pads such that an instruction station may selectively initiate a release of the medication from the electroactive polymer in a desired release pad by sending a signal to a contact point, which then delivers electrical potential to a release pad. Claim 61 provides a method of medicating a patient using the drug delivery system of the present invention. This rejection is overcome in view of Applicant's amendments to claims 54 and 61. Claims 54 and 61 have been amended to require an overlayer to prevent spontaneous release of the drug or medication. Support for this amendment can be found in the specification at p. 6, lines 24-27. Claims 55-60 depend from Claim 54. Claims 62-63 depend from claim 61.

To anticipate the claimed invention, Pickett must teach each and every element of the claimed invention. In Example 3, Pickett teaches the possibility of a multi-pad system. Pickett, however, does not teach an overlayer to prevent spontaneous release, and thus, does not teach the maximization of the amount of drug that can be released to a target. The outer layer in Pickett allows for biocompatibility between the electro-system and the biological environment,

such as a person's blood. The outer layer does not prevent spontaneous release. (*See e.g.* Picket at col. 4, lines 61 –65). Given that the outer layers in the present invention and Pickett serve different functions, they are chemically different. Examples of the outer layer of the present invention are nafion, poly(vinyl acetate), and poly(vinyl butyral). The outer layer in Pickett, on the other hand, typically contains a sugar-type group. (*See e.g.* Picket at col. 4, lines 61 –65).

Further, the structure of Claim 54 allows a high degree of control over timing and dispensing of a target medication. Pickett does not disclose a means to selectively control the release of each of these layers independently as taught in the instant application. The multi-layer electrode disclosed by Pickett does not afford the same degree of control allowed by an electrode according to the instant invention. A stimulating charge provided to the electrode disclosed by Pickett would trigger a delivery of a mixture of all the ionic drugs loaded on that electrode.

Moreover, the inner polymer layer of Pickett provides release by generating protons electrochemically which disturb the active molecule's binding to the polymer, allowing a release. This mechanism, however, will allow only a release that is Faradaic in nature because each proton generated will only be able to work upon a single active molecule site. Pickett is, therefore, restricted to a purely Faradaic delivery of medication while the instant application is capable of both Faradaic and non-Faradaic ("burst") release. Thus, Pickett cannot anticipate the instant application. Applicant respectfully requests that the Examiner withdraw the rejection.

OBVIOUSNESS

In the OA, claims 54-63 stood rejected under 35 U.S.C. § 103(a) as allegedly obvious in view of Miller *et al.* The Office contends that the use of multiple electrodes within a single unit

would be an obvious matter of design, and relies on *In re Harza*, 124 U.S.P.Q. 378 (C.C.P.A. 1960) in support.

To establish a *prima facie* case of obviousness, there must be 1) a suggestion to combine or *modify*, 2) a reasonable expectation of success and 3) the references must suggest all of the claim limitations. MPEP § 2143. (Emphasis added). Mere duplication of Miller *et al.* would not allow simultaneous release of all of the pads, nor a staggered or timed release. In *In re Harza*, the only significant difference between the applicant's invention and the cited reference was the invention's multi-rib structure in comparison to a single-rib structure, with both structures being used for sealing concrete. The court did not establish a *per se* rule that a duplication of parts is obvious; rather, the court held that "a mere duplication of parts has no patentable significance unless a new and unexpected result is produced...." The invention in *Harza* appeared not to produce a new and unexpected result.

In a recent unpublished opinion, the Board of Patent Appeals and Interferences explicitly stated that there is no *per se* rule that a duplication of parts is obvious. The Office must still establish that the "prior art itself must appear to have *suggested* the claimed subject matter." *Ex parte* Grannemain, 68 U.S.P.Q.2d 1219, 1221 (BdPatApp&Int 2003)(Emphasis Added).

In the present application, the Office has not established a *prima facie* case of obviousness. Miller *et al.* do not suggest modifying its invention to produce a multi-release pad system that can be remote controlled. Miller *et al.* also do not suggest the high degree of control over timing and dispensing of a target medication--a new and unexpected result-- that the claimed invention provides. With a multi-release pad system, a skilled artisan can release a drug from different pads simultaneously, in pulse, or staggered. In addition, the pads can carry different drugs, which may respond differently to the same electrical signal, and thus, may be

released at different times and in different amounts. In Miller *et al.*, the examples teach that each pad holds a single drug. Once the drug is dispensed, the pad is removed and reloaded for subsequent use. (Col. 2, lines 63-65). Miller's single pad provides less flexibility and convenience than the claimed invention. The present application allows for more flexibility such as individual releases from a plurality of release pads, staggered release of multiple pads, or a simultaneous release of all the pads. This structure is not disclosed or suggested in Miller *et al.* Applicant, therefore, respectfully requests that the Office withdraw the 35 U.S.C. § 103(a) rejection.

DOUBLE PATENTING

Claims 1-53 stood provisionally rejected under an obviousness-type double patenting rejection as unpatentable over claims 1-53 of the co-pending Application No. 09/929,197. As the pending claims in the present application are claims 54-63, the double patenting rejection should have referred to only claims 54-63. Nevertheless, Applicant would like to defer discussion of the obviousness-type double patenting rejection until any of the pending claims are allowed.

CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant, therefore, respectfully requests that the Office reconsider all the presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action. If the Office believes, for any reason, that personal communication will expedite prosecution of this application, the Office is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

Kimberly H. Lu, Reg. No. 51,973
Thompson Coburn LLP
One US Bank Plaza
St. Louis, Missouri 63101
Telephone: 314-552-6443
Fax: 314-552-6443